DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

5226. Gray, white, and pink tablets containing amphetamine sulfate, thyroid, aloin, and phenobarbital. (F. D. C. No. 39836. S. Nos. 24-971/9 M, 33-532 M.)

INFORMATION FILED: 4-12-57, W. Dist. Okla., against S. Kloster Powell, Lawton, Okla.

SHIPPED: *Gray, white, and pink tablets containing amphetamine sulfate, thyroid, aloin, and phenobarbital,* between 6-13-56 and 8-18-56, from Oklahoma to Missouri and Washington.

CHARGE: 502 (b) (1) and (2)—the tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (e) (2)—the tablets failed to bear a label containing the common or usual name of each active ingredient; and 502 (f) (1) and (2)—the labeling of the tablets failed to bear adequate directions for use and adequate warnings against use; and 503 (b) (4)—the tablets were drugs subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Nolo contendere.

DISPOSITION: 4-24-57. Defendant fined $500 and placed on probation for 5 years.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5227. Cathartic compound pills. (F. D. C. No. 39690. S. No. 37-307 M.)

QUANTITY: 86 cases, each containing 50 1,000-pill btls., at Brooklyn, N. Y.

SHIPPED: 1-5-55, from Edgewater, N. J.

LIBELED: 11-16-56, E. Dist. N. Y.

CHARGE: 502 (a)—the label of the article, while held for sale, bore the statement, "Caution: To be used only by or on the prescription of a physician," which was false and misleading since the statement represented that the article was restricted to prescription sale, when such was not the case; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement; and 502 (f) (2)—the article was essentially a laxative, and its labeling failed to warn that the article should not be taken when severe abdominal pains or other symptoms of appendicitis are present.

DISPOSITION: 6-18-57. Consent—claimed by Chemical Commodities, Inc., Olathe, Kans., and relabeled.

5228. Epsom salt. (F. D. C. No. 39850. S. No. 50-335 M.)

QUANTITY: 59 cases, 24 1-lb. boxes each, 40 cases, 24 ½-lb. boxes each, and 21 1-lb. boxes, at Boston, Mass., in possession of D & L Slade Co.

SHIPPED: 9-28-56, from Midland, Mich.

LABEL IN PART: (Box) "Slade's U. S. P. Epsom Salts."

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*See also No. 5221.

*See also Nos. 5221-5223, 5226.

RESULTS OF INVESTIGATION: The article was shipped in bulk, and after its receipt by D & L Slade Co., it was repacked into the containers described above.

LIBELED: 1–25–57, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use since no indications for use or dosage directions were given; and 502 (f) (2)—the article was essentially a laxative, and its labeling failed to warn that frequent or continued use may result in dependence on laxatives to move the bowels; and the labeling failed also to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present.

DISPOSITION: 2–19–57. Consent—claimed by D & L Slade Co. and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5229. Digitalis tablets. (F. D. C. No. 39683. S. No. 47–311 M.)

QUANTITY: 11 1,000-tablet btls. at Reading, Pa.

SHIPPED: 8–2–56, from St. Louis, Mo., by Keith-Victor Pharmacal Co.

LABEL IN PART: (Btl.) "Enteric coated green 1,000 tablets Digitalis U. S. P. * * * 1½ grains."

RESULTS OF INVESTIGATION: The article was shipped in a bulk container labeled, in part, "Digitalis 1½ gr. Tablets Each Tablet contains Digitalis . . . 1½ gr.," and was repackaged and relabeled as above by the consignee.

Analysis showed that the digitalis potency of the article fell below its professed potency of 1½ grains of U. S. P. digitalis per tablet.

LIBELED: 11–9–56, E. Dist. Pa.

CHARGE: 501 (b)—the article purported to be and was represented as "Digitalis Tablets," a drug the name of which is recognized in the United States Pharmacopeia; and, when shipped and while held for sale, its strength differed from the standard set forth in such compendium; and 502 (a)—the label statement "Digitalis * * * 1½ grains" was false and misleading.

DISPOSITION: 2–7–57. Default—destruction.

5230. Nasal spray. (F. D. C. No. 39486. S. No. 52–694 M.)

QUANTITY: 828 btls. at Newark, N. J.

SHIPPED: 8–16–56, from Brooklyn, N. Y., by Success Chemical Co., Inc.

LABEL IN PART: (Btl.) "20 cc R/W Tyro-Hist Nasal Spray."

LIBELED: 9–25–56, Dist. N. J.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 0.02 percent of tyrothricin; and 502 (a)—the label statement "Contains in Aqueous Isotonic Solution: Tyrothricin . . . 0.02%" was false and misleading as applied to the article, which contained less than 0.02 percent of tyrothricin.

DISPOSITION: 11–14–56. Default—destruction.

5231. Halazone tablets. (F. D. C. No. 39708. S. Nos. 28–250 M, 28–298 M.)

QUANTITY: 400 cases, each containing 3 ctns. of 100 btls. each, at Oakland, Calif.

SHIPPED: On an unknown date, from Chicago, Ill.